

SPL Process Meeting Meeting Minutes October 23, 2013

Chair of today's meeting: Pat Cowall

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

New Discussion Topics:

1. **Daily Med Update:** Daily Med has changed. The search results screen now includes a packager designation ["Original Packager" or "Repackager"]. Do you have any insight as to the reason for this inclusion?

One reason is that there were comments by users regarding the display of what seemed to be the same product information repeated in the DailyMed query results – for multiple repackagers (even though the products are not identical). NLM made a decision to display the original packager first on their website.

The screenshot shows a web browser window with the URL <http://dailymed.nlm.nih.gov/dailymed/search.cfm?startwith=aleve&cc=0&ys=0>. The search results are for "aleve". The search bar at the top right contains "aleve" and a "GO" button. Below the search bar, there are options for "Limits" (Drug Name, NDC Code, Drug Class, Setid) and "Label Type" (Human Drugs, Animal Drugs). The search results are displayed in a table with three rows:

Total Results Found: [Count: 3]	
ALEVE (naproxen sodium) capsule, liquid filled [Bayer HealthCare LLC, Consumer Care]	Original Packager
ALEVE (naproxen sodium) capsule, liquid filled [Bayer HealthCare LLC, Consumer Care]	Original Packager
ALEVE (naproxen sodium) tablet [Cardinal Health]	Repackager

On the left side of the page, there is a sidebar with links to Home, E-mail Label Information, Downloads, Archives, Notify of Updates, Contact Us, Help, Web Services, Browse Drug Classes, and Additional Resources. The Additional Resources section includes links to FDA Structured Product Labeling Resources, SPLIMAGE Specification Version 3.0.2, Report Adverse Event, SPL Format Previewer for Label Authors, and Product Identification System.

At the bottom of the page, there is a footer with the text: "Copyright, Privacy, Accessibility U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894".

For Labels.fda.gov, FDA made the decision to allow users to reduce the amount of results via a simultaneous query of the product proprietary name and company name. That alteration was announced earlier this year.

The diagram shows a central search icon (magnifying glass) with a list of search options arranged around it. The options are:

- Proprietary Name Search
- NDC Number Search
- Active Ingredient Search
- Application Number or Regulatory Citation Search
- Company Search
- Proprietary Name and Company Search

2. Ruth Kirkner posed a question to DRLS (Paul Loebach): Does the establishment need to remain on the DECRS list until the last lot expiry of the products manufactured at the facility or can it be removed upon closure?

Response from Paul Loebach (DRLS): I don't see any reason for it to stay on the books until the products expire if production has already ceased. I recommend you de register when the doors close, so to speak. (or by the following June or December, according to current regs.)

Issues:

- Will this cause a validation issue?
- Several sponsors noted that GDUFA questioned them because their current drug listings contained these closed establishments.--- ie GDUFA said that they weren't self-identifying. GDUFA wanted to collect a fee for these closed facilities. Thus sponsors needed to remove the closed establishments from the current drug listings.
- In order to remove the establishments for a product that is being discontinued, you need to put in an end date for the product – then the product does not need to be linked to a manufacturer.
- Ie they are ensuring that drug listings are kept current

3. Any updates for the FDA accepting alternative identifier numbers to DUNS numbers for Establishment Registration. (Melissa Ignatowski)

New Draft Guidance: Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration

<http://www.fda.gov/downloads/GuidanceComplianceRegulatoryInformation/Guidances/UCM367199.pdf>

Discussion:

- Guidance clearly states that UFI will be the DUNS number.
- Changes take a long time to update.
- Kelly Savage: D&B is typically quite responsive.

4. Ruth Kirkner: Is anyone having issues with the market start and end dates on the NSDE due to the ability to enter only one date for an entire product code. Realize that there is an optional capability to enter each sku separately, but we do not have software to accomplish that at this time. The question is if others are experiencing CMS related issues as a result of the dates in the NSDE list. (Ruth Kirkner)

- End date applies to NDC product code, including all the package codes
- To remove the package code from the NSDE, you remove the specific package code from your SPL file. NSDE will use logic to calculate the market end date as the date that the package was removed from the SPL. There is no technical way to correct dates.
- The optional market start / end dates for specific package codes will not be implemented until FDA announces this. Stay tuned. The stylesheet accommodates this, but the date is not transferred to NSDE.

5. Any comments on the impact of government shutdown.
 - Realize that the NLM Daily Med did not update until Friday October 18th.
 - Perigo: they were not able to check DailyMed during the furlow. But they were able to check the FDA label repository.
 - Those SPLs that were submitted during the shutdown
 - Did anyone have problem with imports??? Was FDA checking shipments – yes one company had a shipment get held up and released.

■ Question for Lonnie: when does the SPL file get validated after you send it to the Gateway. We had a participant that said that one of their labels received a validation error – but appeared on the label repository. Pat to check.

6. Reminder: SPL/DailyMed Jamboree Workshop – Using DailyMed Drug Product Label Data” public meeting -- Monday, October 28th at NIH in Bethesda. Networking event on Sunday, October 27th.

Hotel:

We have negotiated a block of rooms for Sunday October 27th for those of you attending the NLM/SPL Jamboree on October 28th at the Bethesda Double Tree Hotel, a 3 block (half mile) walk or hotel shuttle to NIH/NLM. The hotel details are as follows:

Code: Jamboree

Passcode: JA1

Please call: 1-800-955-7359 or go to the Hilton website and use the JA1 code to obtain the rate. You must contact them directly, not me.

Room rate for Sunday, October 27th, check out Monday, October 28: \$115 plus applicable state and local taxes (currently 13%).

The address is:

DoubleTree by Hilton Hotel Bethesda
- Washington DC

8120 Wisconsin Ave. | Bethesda | MD | United
States 20814

Networking event: <http://www.eventbrite.com/event/8423997403/eivtefrnd>

Sunday, October 27, 2013 from
7:00 PM to 10:00 PM (EDT)

Union Jack's of Bethesda, MD
4915 Saint Elmo Avenue
Bethesda, MD 20814

7. Janet Riffits (McNeil): Is a new NDC needed?

Situation: We are evaluating a name change for a current product, formulation of product and all other factors remain the same.

Current Proprietary Name (drug listed): Product Cold & Flu

Proposed New Name: Product Cold + Flu

Questions:

- Will this fail SPL validation when updating the drug listing and a manual override would be needed?
- Would it be required that a new NDC number be given?

Comments:

Perrigo: they do many many product name / title changes. In the eyes of the FDA, this is a new product and requires a new NDC code. They do this routinely. They always a new NDC code- based on 21CFR207 regulations – product title is one of the criteria for needing a new NDC.

But this is getting stickier with NDC code duplication - ie multiple manufacturers are assigning NDC codes for the same marketer. .

Suggest sending question to Lonnie or eDRLS – asking if this is a name change that requires a new NDC.

Note: product name cannot contain these symbols.

Holdovers from the last meeting:

8. **D&B data issues** – Dale lanetti (Merck) is part of a pilot program and had a number of issues. Dale sent whole file to D&B to get their help in resolving their issues.
 - D&B - compared all data from all sites – so that they could determine the differences.
 - Talked through all the issues. D&B is investigating several of their issues. They are going to talk to FDA to determine if there is some flexibility in terms of allowing differences.
 - Merck will not change addresses or names, but will make minor changes in addresses if the address is still consistent. Merck also needs several new DUNS numbers because the addresses didn't match up.

***Hold to next meeting

9. Dale lanetti: I was wondering if anyone in the group has had the opportunity to request a new FEI number for a site, and exactly what the process is. I have heard different stories and would like to know if anyone has actually done it since SPL has been in use.

***Hold to next meeting

Charisse Kasser was involved with writing the new guidance. The FEI number will not go away, at least in the near future. At any event, the FEI will be used internally at FDA in their computer systems. Many FDA ORA systems use the FEI numbers, so the FEI number will stay.

10. Ruth Kirkner: Download xml from DailyMed. Has anyone had problems with text being cut off from the downloaded version of SPL – eg long black box warning. All text exists on Daily Med, but the downloaded version is wrong.
 - a. It sounds like the stylesheet is not handling the text properly
 - b. Suggest contacting DailyMed to alert them of the problem.
 - c. Ruth will let us know outcome

Announcements:

ESG Issue

- ESG REG has confirmed that there is now a known issue with ESG WebTrader's Acknowledgements.
- There is a problem where user Acknowledgements are not displayed in the MySubmissions Screen, but sent to the Other Documents Folder in some but not all cases.
- ESG REG are aware of the problem and are working to fix it. In the meantime, please keep this in mind when sending submissions via the FDA WebTrader to check your Other Documents Folder for the Acknowledgements.

SPL/DailyMed Jamboree Workshop

NLM is sponsoring a public meeting, "SPL/DailyMed Jamboree Workshop, on October 28, 8:30 to 3:30 – Using DailyMed Drug Product Label Data". Representatives from the brand name, generic name and OTC drug industries will speak, as well as the FDA, the NLM and possibly other government agencies.

- Terry Brunone, Marcia Howard, Virginia Hogan (generics) and others will be presenting.
- Note: I tried to register last week and the online spots were full. I was put on a wait list. There were still spots available to attend in person, as of last week.
- Marcia Howard would like to know of any unique ways they are using information from Daily Med.

DIA Labeling Conference -- focusing on a number of global labeling topics: how to write device labeling, patient labeling, new EU Pharmacovigilance influence on labeling, Health Canada, PMDA, etc. Steve Bass will be sending more information on this.

Timing: April 8-10, 2014

Where: Washington area